K062721

510(K) Summary

Submitter: Greenton (London) Ltd.
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UNITED KINGDOM

NOV 21 2006

Contact: Robert T. Handren, Jr., M.S.
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Date Summary Prepared: July 17, 2006

Device Trade Name: Greenton Ecolite IPL System

Common Name: Pulsed Light system

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Device: Quanta System Eterna Giovinezza (K051113)

Device Description: The Greenton Ecolite IPL System is a pulsed light, wavelength range adjustable system. It provides selectable handpiece aperture sizes for a variety of applications. Light emission activation is by foot switch. Overall weight of the system is 110 lbs., and the size is 13.8" X 19" X 40". Electrical requirement is 110 VAC, 15A, 50/60 Hz, single phase.

Intended Use: The Greenton Ecolite IPL System is indicated for permanent hair reduction, photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions and inflammatory acne (ache vulgaris).

Comparison: The Greenton Ecolite IPL System is identical to the Quanta System Eterna Giovinezza, has the same indications for use, the same principle of operation, and the same wavelength range and pulse energy range as the predicate device.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Greenton Ecolite IPL System raises no new safety or effectiveness questions in comparison to the predicate device.

Additional Information: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Greenton (London) Ltd
% Handren Associates, Inc.
Robert T. Handren, Jr., M.S.
President
5818 Princess Caroline Place
Leesburg, Florida 34748

Re: K062721
Trade/Device Name: Greenton Ecolite IPL System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 2, 2006
Received: September 12, 2006

Dear Mr. Handren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 062721

Device Name: Greenton Ecolite IPL System

Indications For Use:

The Greenton Ecolite IPL System is indicated for permanent hair reduction, photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions and inflammatory acne (ache vulgaris).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062721